PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference K2197 PCT	**FOR FURTHER ACTION** See Form PCT/IPEA/416	
International application No. PCT/EP2004/009100	International filing date *(day/month/year)* 13.08.2004	Priority date *(day/month/year)* 14.08.2003
International Patent Classification (IPC) or national classification and IPC B05C17/005, A61C9/00, A61B17/00		
Applicant 3M ESPE AG et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 6 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
01.09.2005	15.12.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Roldán, J Telephone No. +31 70 340-2740

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/009100

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-18	as originally filed

Claims, Numbers

10-47	received on 01.09.2005 with letter of 01.09.2005
1-9	filed with telefax on 01.12.2005

Drawings, Sheets

1/19-19/19	as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☒ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☒ the claims, Nos. 48-50
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 18-47

because:

☒ the said international application, or the said claims Nos. Fees have not been paid. relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees, the applicant has:
   - ☐ restricted the claims.
   - ☐ paid additional fees.
   - ☐ paid additional fees under protest.
   - ☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-17 .

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	5-11,15-17
	No:	Claims	1-4 ,12-14
Inventive step (IS)	Yes:	Claims	5,7-11,15-17
	No:	Claims	1-4,6,12-14
Industrial applicability (IA)	Yes:	Claims	1-17
	No:	Claims	

2. Citations and explanations (Rule 70.7):

   see separate sheet

Re Item IV.

This Authority considers that there are 4 inventions covered by the claims indicated as follows:

Group I: Claims 1-17: Syringe comprising a mixing tip and a cartridge wherein said mixing tip is integrally formed as one part with said cartridge.
Group II: Claims 18-23: Syringe comprising a mixing tip and a cartridge wherein said mixing tip is connectable to said cartridge.
Group III: Claims 24-42: Syringe comprising a static mixer and a cartridge, wherein said static mixer is integrally connected to said cartridge.
Group IV: Claims 43-47: Syringe comprising a mixing tip and a two-compartment cartridge with connectable passageways.

The reasons for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:

Document US 5,743,436 is considered to represent the closest prior art, with regard to the features of claim 1 and discloses a syringe suitable for unitary dosage and multi-component material, comprising a cartridge, a mixing tip, a static mixer and a plunger.

The special technical features, as defined in Rule 13.2 PCT, of the first group of claims, are considered to be a syringe comprising a mixing tip and a cartridge, wherein said mixing tip is integrally formed as one part (page 7 bottom) with said cartridge, and solve the problem of providing a syringe for multi-component material comprising a minimum number of easy to manufacture parts (see pages 1 and 2 in the description).

The special technical features, as defined in Rule 13.2 PCT, of the second group of claims, are considered to be a syringe comprising a mixing tip and a cartridge, wherein said mixing tip is connectable to said cartridge, and solve the problem of reducing the overall length of the syringe during storage and thus saving space (page 11 paragraph 4 of the description).

The special technical features, as defined in Rule 13.2 PCT, of the third group of

claims, are considered to be a syringe comprising a static mixer and a cartridge, wherein said static mixer is integrally connected to said cartridge and solve the problem of preventing the user from the risk of using a wrong mixer with the cartridge (page 14 bottom, of the description).

The special technical features, as defined in Rule 13.2 PCT, of the fourth group of claims, are considered to be a syringe comprising a static mixer and a two-compartment cartridge, wherein said compartments and mixer are connectable through passageways, and solve the problem of homogeneously mixing powder and liquid (page 15 middle, of the description).

These special technical features are neither identical (see above) nor corresponding since they are directed to solving different problem (see above). Therefore the application is considered to lack unity, as required by Rule 13.1 PCT.

Re Item V.

Reference is made to the following documents:

D1: US-A-5 743 436 (CARUFEL ROGER J ET AL) 28 April 1998 (1998-04-28)
D2: WO 03/041605 A (3M ESPE AG (DE)) 22 May 2003 (2003-05-22)
D3: GB-A-2 086 248 (HILTI AG) 12 May 1982 (1982-05-12)
D4: US-A-4 676 657 (BOTRIE ET AL) 30 June 1987 (1987-06-30)
D5: EP-A-0 444 247 (W A KELLER PROZESSTECHNIK ; CROWN DELTA CORP (US)) 4 September 1991 (1991-09-04)
D6: US-A-3 738 535 (NICHOLLS A,US) 12 June 1973 (1973-06-12)
D7: US-A-3 587 982 (HUGH W. CAMPBELL) 28 June 1971 (1971-06-28)
D8: EP-A-0 815 802 (MINNESOTA MINING AND MANUFACTURING COMPANY) 7 January 1998 (1998-01-07)
D9: US-A-4 690 306 (STAEHELI ET AL) 1 September 1987 (1987-09-01)

1 INDEPENDENT CLAIM 1

1.1 The present application does not meet the criteria of Article 33(1) PCT, because the

subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.
Document D1 discloses (the references in parenthesis applying to this document):

A unit-dose syringe for a multi-component material, comprising:
a cartridge (12) having a front end (52) and a rear end (right in Fig. 4), and having a compartment (50) for each component,
a static mixer (56) connectable (see column 5, line 20) with said cartridge at its front end (Fig. 4),
a mixing tip (54) being integrally connected (see column 5, paragraph 5) to the cartridge at said front end (52) of said cartridge and receiving said static mixer (56), said mixing tip and said cartridge being integrally formed as one part,
and a plunger (51,42) being located in the inactivated state of the syringe, at said rear end of said cartridge, and movable towards the front end of said cartridge for dispensing material from said cartridge through said mixing tip.

3 DEPENDENT CLAIMS 2-4, 6, 12-14
Dependent claims 2-4, 6, 12-14 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

3.1 Claims 3,4, 12-14 are not novel with regard to D1 since it discloses (the references in parentheses applying to this document):

-static mixer with helix (Fig. 4, 56),
-static mixer with an (not defined in claim 1) outlet tip (52, when the mixer is connected),
-mixing tip is an extension of a cartridge (it is indeed flared, extending from both compartments)
-mixing tip comprises the outlet tip (Fig.4)
-compartments connected by passageways (52, Fig. 4)

3.2 Features "mixer with closure plugs" and "collapsible mixer" are described in document D2 as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal option to include these features in the syringe described in document D1 in order to solve the problem

posed of sealing the cartridges with a static mixer. Therefore claims 2 and 6 lack the required inventive step (Article 33(3) PCT).

4 DEPENDENT CLAIMS 5, 7-11, 15-17

The combination of the features of dependent claims 5, 7-11, 15-17 provide means (hinge) for accessing the mixer for replacement or inspection. These features are neither known from, nor rendered obvious by, the available prior art, since none of the documents cited in the search report discloses nor suggests the features of said claims.

< the front end of said cartridge >

CLAIMS

1. Unit-dose syringe for a multi-component material, comprising:
a cartridge having a ~~first~~ front end and a ~~second~~ rear end, and having a compartment for each component,
a static mixer connectable with said cartridge at its ~~first~~ front end,
a mixing tip being integrally connected to the cartridge at said ~~first~~ front end of said cartridge and receiving said static mixer, said mixing tip and said cartridge being integrally formed as one part, and
~~a plunger~~ [for dispensing material from said cartridge through said mixing tip] ~~said~~ plunger being ~~arranged~~ located in the inactivated state of the syringe, at said ~~second~~ rear end of said cartridge, and moveable towards <->[-]

2. The syringe of claim 1, wherein said static mixer comprises closure plugs at is rear end for closing the outlet openings of said compartments of said cartridge.

3. The syringe of claim 1 or 2, wherein said static mixer comprises a mixing helix.

4. The syringe of claim 3,wherein said static mixer comprises an outlet tip at the front end of said mixing helix.

5. The syringe of claim 4, wherein said outlet tip is connected to said mixing helix by means of a hinge.

6. The syringe of any of claims 1 to 5, wherein said static mixer is collapsible.

7. The syringe of claim 4 or 5, wherein said outlet tip of said static mixer projects from the front end of said mixing tip when said static mixer is received in said mixing tip.

8. The syringe of claim 4, 5, or 6, wherein said outlet tip of said static mixer is accommodated within said mixing tip during storage of said syringe.

9. The syringe of claim 8, wherein said front end of said mixing tip and said outlet tip of said static mixer comprise corresponding retention means that allow said outlet tip to

project beyond said front end of said mixing tip upon activation of said syringe but prevent that said outlet tip completely extends beyond said mixing tip.

10. The syringe of claim 9, wherein said retention means at said front end of said mixing tip comprises a recess in the wall of said mixing tip, and said retention means at the outlet tip comprises a projection at the circumference of the rear end of said outlet tip, said projection being engagable by said recess.

11. The syringe of any of claims 1 to 10, wherein said mixing tip is connected to said cartridge by means of a hinge.

12. The syringe of any of claims 1 to 11, wherein said mixing tip forms an extension of a first of said compartments of said cartridge.

13. The syringe of claim 1, 2, 3, or 12, wherein said mixing tip comprises at its front end said outlet tip.

14. The syringe of claim 12 or 13, wherein said first and a second compartment are connected by a passageway being provided adjacent said first end of said cartridge.

15. The syringe of claim 14, wherein said second compartment comprises a plug sealing said second compartment against that opening of said passageway facing towards the interior of said second compartment.

16. The syringe of claim 14 or 15, wherein said static mixer comprises at its rear end a plug sealing said first compartment against that opening of said passageway facing towards the interior of said first compartment.

17. The syringe of claim 16, wherein activation of said syringe by said plunger moves said plugs along the longitudinal direction of said syringe in order to free said passageway so that material is allowed to flow from said compartments into said mixing tip.

18. Unit-dose syringe for a multi-component material, comprising:

a cartridge having a first end and a second end, and having a compartment for each component,

a mixing tip being connectable with said cartridge at its first end and receiving a static mixer, and

a plunger for dispensing material from said cartridge through said mixing tip, said plunger being arranged at said second end of said cartridge,

wherein said cartridge comprises a recess at its first end in longitudinal direction for receiving the rear end of said mixing tip, and

wherein said cartridge comprises radial openings in the wall of said recess providing passageways from said compartments to said recess.

19. The syringe of claim 18, wherein said mixing tip comprises radial openings that correspond to said radial openings in said recess wall to provide passageways from said compartments into said mixing tip.

20. The syringe of any of claims 18 or 19, wherein said static mixer comprises a mixing helix.

21. The syringe of claim 202, wherein said static mixer comprises a spacer at the rear end of said mixing helix, said spacer extending along the longitudinal axis of said static mixer.

22. The syringe of claim 21, wherein said static mixer comprises a closure element at the rear end of said spacer.

23. The syringe of claim 22, wherein said spacer extends in longitudinal direction along the width of said passageways at said rear end of said mixing tip such that closure element is located rearwards of said passageway openings.

24. Unit-dose syringe for a multi-component material, comprising

a cartridge having a first end and a second end, and having a compartment for each component, said compartments extending between said first end and said second end;

a static mixer being integrally formed with said cartridge at said first end;

a plunger for dispensing material from said cartridge, said plunger being arranged at said second end of said cartridge; and

a mixing tip connectable to said cartridge at said first end of said cartridge and receiving said static mixer.

25. The syringe of claim 24, wherein said each compartment of said cartridge comprises outlet openings at the first end of said cartridge.

26. The syringe of claim 25, wherein said outlet openings of said compartments are directed along the longitudinal axis of said syringe.

27. The syringe of claim 24, 25, or 26, wherein said mixing tip comprises an axially acting rotary slide valve at its end being connectable to said first end of said cartridge.

28. The syringe of claim 27, wherein said axially acting rotary slide valve comprises passageways and seal areas that are alternately alignable with said outlet openings of said cartridge compartments.

29. The syringe of claim 27 or 28, wherein said valve comprises a locking mechanism being engageable with a corresponding locking mechanism at said first end of said cartridge.

30. The syringe of claim 29, wherein said locking mechanism at said cartridge comprises pins that are engagable in corresponding recesses forming said locking mechanism of said valve.

31. The syringe of claim 30, wherein said pins and said recesses are formed such that a thread lock is obtained interlocking said mixing tip and said cartridge in longitudinal direction of said syringe.

32. The syringe of claim 25, wherein said outlet openings of said compartments are directed transverse to the longitudinal axis of said syringe.

33. The syringe of claim 32, wherein said mixing tip comprises a radially acting rotary slide valve at its end being connectable to said first end of said cartridge.

34. The syringe of claim 33, wherein said radially acting rotary slide valve comprises a body member forming a cavity that corresponds to the outer surface of said cartridge in the area of its firs end for receiving said first end of said cartridge.

35. The syringe of claim 34, wherein said wall of said cavity comprises recesses along the longitudinal axis of said body member, said recesses being alignable with said outlet openings of said cartridge for forming passageways from said compartments of said cartridge to said static mixer.

36. The syringe of any of claims 1 to 35, wherein said cartridge comprises at its outer surface extensions or protrusions being sized and shaped to provide said cartridge with a substantially circular circumferential outer surface.

37. The syringe of any of claims 1 to 36, wherein said cartridge has a rounded circumferential surface, and comprises at least one internal separation wall.

38. The syringe of any of claims 1 to 36, wherein said compartments are arranged concentrically.

39. The syringe of any of claims 1 to 38, wherein said plunger comprises a separate piston for each compartment of said cartridge.

40. The syringe of any of claims 1 to 39, wherein said cartridge is made from an elastic material.

41. The syringe of claim 40, wherein said elastic material is a thermoplastic elastomer.

42. The syringe of any of claims 1 to 41, wherein said plunger is made from a rigid material.

43. Unit-dose syringe for a multi-component material, comprising

a cartridge having a first end and a second end, and having a at least a first compartment for a first component and a second compartment for a second component, said compartments extending between said first end and said second end;

a plunger for dispensing material from said cartridge, said plunger being arranged at said second end of said cartridge; and

a mixing tip connectable to said cartridge at said first end of said cartridge and receiving a static mixer;

wherein said first compartment is connectable to said second compartment by a first passageway, and said second compartment is connectable to said mixing tip by a second passageway.

44. The syringe of claim 43, wherein a first compartment of said cartridge comprises said first passageway at said first end of said cartridge.

45. The syringe of claim 44, wherein said first compartment and a second compartment are rotatable relative to each other.

46. The syringe of claim 45, wherein the wall of said first compartment comprises a first channel being inclined with regard to the longitudinal axis of the syringe, and wherein the wall of said second compartment comprises a second channel being inclined with regard to the longitudinal axis of said syringe, and wherein rotational movement of said first compartment relative to said second compartment brings said first inclined channel and said second inclined channel into alignment to provide a passageway from said first to said second compartment.

47. The syringe of any of claims 1 to 46, being pre-filled with a multi-component dental material.